

Message Text

UNCLASSIFIED

PAGE 01 STATE 215786
ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-09 /028 R

DRAFTED BY DHEW/FDA: JJZAIC:VO

APPROVED BY OESEN/EN: DKING

DHEW/PHSOAS/OIH: RFISCHER

EUR/NE:DGOODMAN(INFO)

EUR/WE:MLISSFELT(INFO)

EUR/CE:SKLINGAMAN(INFO)

EUR/NE:WNEWLIN(INFO)

-----102694 250213Z /64

P 242049Z AUG 78

FM SECSTATE WASHDC

TO AMEMBASSY HELSINKI PRIORITY

AMEMBASSY PARIS PRIORITY

AMEMBASSY BONN PRIORITY

AMEMBASSY BRUSSELS PRIORITY

AMEMBASSY THE HAGUE PRIORITY

UNCLAS STATE 215786

E.O. 11652: N/A

TAGS: OGEN, OCON, OTRA, EIND, ETRD, FI, FR, GW, BE, NL

SUBJECT: FDA REPRESENTATIVES PROVIDING TECHNICAL AND
CONSULTATIVE ASSISTANCE TO EUROPEAN X-RAY MANUFACTURING
FACILITIES

1. FDA ADVISES THAT EDWIN A. MILLER, CHIEF, COMPLIANCE
EVALUATION SECTION, AND DR. ROBERT M. GAGNE, REGULATORY
OFFICER, X-RAY PRODUCTS BRANCH, DIVISION OF COMPLIANCE,
BUREAU OF RADIOLOGICAL HEALTH WILL BE IN EUROPE SEPTEMBER
9-23, 1978

2. MR. MILLER AND DR. GAGNE WILL VISIT 5 X-RAY MANUFACTUR-
UNCLASSIFIED

UNCLASSIFIED

PAGE 02 STATE 215786

ING FACILITIES TO DETERMINE IF THE FIRM'S FACILITIES AND
OPERATIONS ARE IN ACCORDANCE WITH CURRENT GOOD MANUFACTUR-
ING PRACTICE REGULATIONS AND WILL REPORT ANY SIGNIFICANT
DEVIATIONS WHICH WOULD AFFECT THE SAFETY AND/OR EFFICACY
OF X-RAY EQUIPMENT BEING IMPORTED INTO THE UNITED STATES.

3. ITINERARY AS FOLLOWS:

SEPTEMBER 9,1978 - ARRIVE HELSINKI, FINLAND
SEPTEMBER 11 VISIT PALOMEX (SIMENS)
SEPTEMBER 12 - VISIT SOREDEX OY
SEPTEMBER 13 - TRAVEL HELSINKI, FINLAND TO PARIS, FRANCE

SEPTEMBER 14-15 VISIT CGR MEDICAL
SEPTEMBER 17 TRAVEL PARIS, FRANCE TO ESSEN, WEST GERMANY
SEPTEMBER 18-VISIT CGR MEDICAL; TRAVEL ESSEN, WEST
GERMANY TO ANVERS, BELGIUM
SEPTEMBER 19-VISIT CGR MEDICAL
SEPTEMBER 20 - VISIT ORGANON TEKNIKA; TRAVEL ANVERS, BELGIUM
TO ENDHOVEN HOLLAND
SEPTEMBER 21- VISIT PHILIPS MEDICAL; TRAVEL EINDHOVEN,
HOLLAND TO HAMBURG, WEST GERMANY
SEPTEMBER 22 - VISIT PHILIPS MEDICAL
SEPTEMBER 23 - DEPART HAMBURG, WEST GERMANY FOR WASHINGTON,
DC.

4. ASSISTANCE OF EMBASSIES WILL NOT BE REQUIRED. CHRISTOPHER

UNCLASSIFIED

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: TECHNICAL ASSISTANCE, VISITS
Control Number: n/a
Copy: SINGLE
Draft Date: 24 aug 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE215786
Document Source: CORE
Document Unique ID: 00
Drafter: JJZAIC:VO
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780347-0905
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780826/aaaaavza.tel
Line Count: 81
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 844e105c-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 1629884
Secure: OPEN
Status: NATIVE
Subject: FDA REPRESENTATIVES PROVIDING TECHNICAL AND CONSULTATIVE ASSISTANCE TO EUROPEAN X-RAY MANUFACTURING FACILITIES
TAGS: OGEN, OCON, OTRA, EIND, ETRD, FI, FR, GE, BE, NL, US, (MILLER, EDWIN A), (GAGNE, ROBERT M)
To: HELSINKI PARIS MULTIPLE
Type: TE
vdkgvgwkey: odbcr//SAS/SAS.dbo.SAS_Docs/844e105c-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
Declassified/Released
US Department of State
EO Systematic Review
20 Mar 2014
Markings: Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014